

THE HISTORICAL EVOLUTION OF THE ROMANIAN PHARMACEUTICAL LEGISLATION BETWEEN 1874-1948

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Abstract

It has been noted that the pharmaceutical legislation suffers continuous modifications due to the changes and influences of social life.

This article has been written in order to analyze the Pharmacy and Medicine regulations in Romania covering the period 1874-1948, years that are important as reference points, namely the elaboration of the first health law in 1874 and the nationalization made in 1948 in Romania.

The laws issued in this period cover numerous guidelines concerning pharmaceutical field.

In this paper various aspects from normative acts that refer to pharmaceutical activity in Romania are taken into consideration, namely: the right of ownership of a pharmacy, the pharmacy concession, the operation authorization, the pharmacy staff, disciplinary punishments and a statistic situation issued when a general census of pharmacists was performed in 1941.

Rezumat

Legislația farmaceutică este în continuă transformare, datorită schimbărilor și influențelor vieții sociale.

În acest articol ne-am propus să analizăm reglementările care au vizat farmacia și medicamentul în perioada 1874-1948 în România, ani care reprezintă puncte de reper importante, și anume, elaborarea primei legi sanitare (1874) și naționalizarea efectuată în 1948 în România.

Legile sanitare emise în acest interval de timp conțin numeroase norme care privesc domeniul farmaceutic.

În cadrul lucrării am avut în vedere aspectele diverse prevăzute de actele normative care reglementează activitatea farmaceutică românească, și anume: dreptul de proprietate asupra farmaciei, obținerea autorizației de funcționare, personalul farmaciei, pedepsele disciplinare, precum și o statistică emisă cu ocazia recensământului general al farmaciștilor din 1941.

Keywords: pharmaceutical legislation, pharmacy concession, pharmacy, medicine, nationalization, history.

Introduction

Over time, the health system has experienced numerous regulations which did not last for many years, the main reason being the continuous change of the society.

To easily describe the development of the regulations of the health system from the first law until nationalization, the following table could be followed up:

Table I
Health / Pharmaceutical legislation - from the first law (1874)
until nationalization (1949)

Item no.	Name of regulation	Changes/Completions	Pharmaceutical field regulation
1	1874 - Health Law O.G. no.131 - June 1874		Chapters: III, T XIII; XIV; XV, XVIII
2	1885 - Health Law O.G. no.2-3 April 1885	Art.80, 84, 85, 87, 88, 89, 90, 91, 92	Art.80, 84, 85, 87, 88, 89, 90, 91, 92
3	1887 - Health Law O.G. no. 215-30 December 1887	Art. I, II, III	Art. I, II, III
4	1893 - Health law with changes from 1896 and 1898 - O.G. from 18 th of June 1893 with changes from 22 nd of February, 1896 and 24 th of May 1898.	Title V, The pharmacy exercise, cap. XIV and XV Reg.	Title V The pharmacy exercise, cap. XIV and XV
5	1910 - Health Law, D.R. no. 3804/1910 O.G. no. 211 December 1910	35 Reg.	Title V The pharmacy exercise [p.181x...]
6	1921 - Law for suspension of the 122 article from the Health Law of 1910 during 4 months. D.R. no. 3284/July 1921 O.G. no. 92/1921	Decision 20567/07.1921 Decision 24043/09.1921	
7	1926 - Law for changing some articles from the Health Law DR 1240-03.1926 O.G: 68-03.1926	Art.: 112, 115, 116, 117 -119, 124	Art.: 112, 115, 116, 117 - 119, 124
8	1928 - Law for the fight against drugs abuse. DR 1095/1928 and O.M. 90- 04.1928	Regulation of state monopoly for drugs 1933 C.I. drugs ratified by Romania in 1933	
9	Health and care law no. 236/1930, O.G. no. 154 from 14 th of July 1930		T. II The pharmaceutical institution, with XIII cap. from article no. 359 to 433

Item no.	Name of regulation	Changes/Completions	Pharmaceutical field regulation
	The College pharmaceutical regulation from Romania	DR no.1127/ April 1931 April 1931 and OG no. 89/1931	
9'	Regulation for the Pharmacies operation, internal organization and control DR no. 1320-1933, OG no.106, May 1933.	Regulation for the official pharmaceutical tax DR no 1321 – 1933, OG no. 106, May 1933	
	Regulation of state monopoly of drugs	DR no. 2111/1933 OG no. 167/1933	
10	1935 - Health and Care Law –OG.140 – 06 1935	DL no. 271 from 11.1941, the changing of the 363, 365, 367-369 and 371-372 articles. OG 140 22.07.1935	Art. 350-425 Reg. for the pharmacy operation OG 70-23.03.1934
11	1941 - Law act OG no 296-XII 1941 1941 - Law act OG no 284 -XI 1941		Pharmacies classification Regulation regarding the pharmacies unification.
12	1942- Law act OG 47 – II 1942		Competitions 60-70 Pharmaceutical articles
13	Law no. 189/1943 for the health organization of the state, OM no 171 from 23 rd of March 1943. The Law act 782/1943 for the Law promulgation 183/1943		
14	59299/1950 Decision for the pharmacies operation and organization		XIII – chapters (105 articles)

OG – Official Gazette; DR – Royal Decree; OM – Ministry Order; CI – International Convention; DL – Law/Decree; Reg – Regulations; T – Title; Art – Article; Cap – Chapter; p – Paragraph.

Regarding the pharmaceutical area, before the first published sanitary law, the authorities recommended the use of provisions from pharmaceutical regulatory documents, especially the Austrian Pharmacopoeia from 1780 [2].

The first Romanian sanitary law

From the first Romanian sanitary law (1874), it can be found that the pharmaceutical practice area plays an important role. Thus, in the Chapter

III of the Health Law of 1874 (in 28 articles and 4 titles) are legislated aspects regarding: “pharmacy supervision”, “new establishment and termination of concessions”, “pharmaceutical personnel”, etc.

First of all, it has to be analyzed the pharmaceutical regulations in two different periods with regard to the type of ownership of pharmaceutical units and how they could be established and/or transmitted to others. From the first Romanian sanitary (1874) law until the nationalization (1949), the establishing of a pharmacy was only permitted to a licensed person and through contest; the license could only not give the permission to establish a pharmacy. The law of 1885 gave the right to sell the concession of a pharmacy only by pharmacists who had obtained it through a contest; they could have sold it during their lives only to other pharmacists and only in specific circumstances. Moreover, this right could not be given to the widow and children after death of the one who bought the concession through contest. The 1885 law did not allow the transmissibility of the right to open, to hold and to rent the pharmacy as a private good forever. The next law, from 1887, interprets more closely the one from 1885, setting clearly the restriction of selling the right of a pharmacy concession, when it has been obtained through contest, only after it has been opened and ran personally for at least ten years by the concessionaire.

This law is the one which establishes the right to rent a pharmacy only for the widow and children’s concessionaire. The law stated that the authorization was only valid for the person, the location and the indicated place. The drugs had to meet all the requirements of the Romanian Pharmacopoeia and their price had to be set by the pharmaceutical fee approved and published in the Official Gazette [1,2].

The 1885 and 1887 Romanian health laws

The 1885 and 1887 health laws are re-interpretations of the one issued in 1874. The first time when the concession of opening a pharmacy was given, was issued on the 21st of May 1885 and the next one in November 1890 [1,3,4].

In comparison with the 1874 sanitary law, the one from 1885 specifies the following:

- the control of the pharmacies should be done not only by the Supreme Council, but also by the chemical-pharmaceutical commission.
- the pharmacists’ academic titles obtained abroad would be checked by the Health Supreme Council and approved by the Minister of the Interior and not by the Minister of Cults and Instruction;

- the assistants' certificates obtained abroad would not be valid in the country;
- the pharmacist, who has opened a pharmacy as a result of a concession through contest, could not participate in another contest;
- the concession for opening a pharmacy will be given to one specific person, for a specific location and, consequently the words "for life" from the law of 1874, have been removed;
- a fine of 100 to 2000 lei and closing of the pharmacy were the sanctions for the pharmacists who were leading a pharmacy without authorization from the Minister, for the pharmacists who allowed in their unit pharmacists or assistants without recognized titles in the country, or unregistered students at a pharmacy college [1,2].

According to the sanitary law from 1893, which was successively modified in 1896 and then in 1898, the pharmacies could have been leased only by Romanian pharmacists who met the specific experience and age requirements. In villages without a doctor, the pharmacies could not be established. In cities where pharmacies were already established, other pharmacies could have been opened only if the proportion of one pharmacy per 5000 citizens was respected.

In respect of previous laws, the 1910 law introduced a new category: the subsidiary pharmacy; this could be leased only to the owners of the parent pharmacies and could be headed by an administrator, but it could not be transferred or sold. The 1921 law was issued to adjourn the article no. 122 from the 1910 sanitary law which was referring to the way in which a pharmacy could be leased or moved [5,6]. Later on, the law of 1926 has also made some changes to the law of 1910, all the modified articles being related to the establishment and authorization of the pharmacies. The change or the transfer of the pharmacies were allowed only if the person who led the unit would have done this for at least five years and he would have had the express approval of the Ministry of Health and Social Welfare (MHSW). No licensed pharmacist could have held two pharmacies at the same time [7,8].

The interwar period (1918-1939)

The law no. 236/1930 stated that "The pharmacies operate according to the law, regulations and health ordinances in force, under the Ministry of Labor, Health and Social Welfare control". The same law classifies the pharmacies, as follows:

- a) urban and rural public pharmacies - to meet the public demands;

- b) pharmacies for clinics, hospitals, Constituency and Social Insurances houses - for their own needs;
- c) hand pharmacies - to meet people's urgent needs in villages without public pharmacies.

Also, there were specified the conditions for pharmacists who were allowed to practice and the interdiction of "having at the same time only one pharmacy as property, rent or manage; also they may not have, rent or manage at the same time a drug store."

Regarding the drugs it was required that all the pharmacies had all the drugs, chemicals, galenical preparations, reagents and all the preparations from the Romanian Pharmacopoeia in force; these had to meet all the quality and purity conditions required by Pharmacopoeia in force. Also, the pharmacies had the obligation to release the special medicines based only on doctors' prescriptions. The medicines prices would have been set by the Minister with the chemical-pharmaceutical endorsement and it would have been included in the official pharmaceutical fee. For special medicines, a fee up to 20% above the price was set up [9].

The pharmacy staff consisted of:

- a) chief pharmacist;
- b) pharmacist probationer;
- c) pharmacist helper;
- d) pharmacy assistant;
- e) student in pharmacy (within the pharmaceutical practice)

The pharmacies supervision and control was performed by the Minister through:

- a) chemical-pharmaceutical institutes;
- b) pharmaceutical department from the Minister;
- c) the health bodies of the local ministerial departments;
- d) the county control commissions.

The regulation for the operation, internal organization and pharmacies control from 1933 provided some additional details to the law of 1930. There were provided deadlines to process the applications for the relocation of pharmacies (15 days); there were also provided penalties for moving the pharmacies without the Ministry of Health and Social Welfare (MHSW) authorization, temporary closing of the pharmacy and losing the right of practice for a limited time established by the Regional Commission for Discipline for the chief pharmacist. The same regulation provided that the public pharmacies program was mandatory from 8 to 13 and from 15 to

20, and on Sundays and legal holidays, the pharmacies would have been closed except those who were on duty. Where there were several pharmacies, the night work would have been done by rotation, and where there was just one public pharmacy, the night work was mandatory every night. The night service for pharmacies was established by the Municipal or County College by rotation. It was prohibited the exposure on window of special drugs, bandages or any substance or therapeutic products. The regulation also specified the number, the type and the destination of pharmacy rooms and the mandatory registers for each pharmacy, as well the staff who could carry on the activity in that unit [10,11].

The health and care law of 1935 brought, in addition to the law of 1930, the seasonal pharmacy for the spa and climatic locations where no public pharmacy existed; the seasonal pharmacy operated as a subsidiary of a pharmacy from that region only between 1st of May and 1st of October [12,14].

The Probationer Pharmacist could replace for up to six months the chief pharmacist and could lead a seasonal pharmacy. The students from the 2nd year of study could be considered pharmacy assistants, if they were “active students with a regular frequency” [15].

The law of 1935 provided five types of disciplinary punishments:

1. admonition;
2. penalty / fine from 1.000 to 20.000 lei;
3. the temporary loss of the right of practice as a pharmacist or druggist;
4. the temporary closing of the pharmacy or drugstore;
5. the permanent loss of right of practice as a pharmacist or druggist.

According to the 1941 Decree Law regarding the pharmacy unification, the pharmacies situation was as follows: in the Old Kingdom of Romania there were 198 new established pharmacies and 204 pharmacies which belonged to Jews, and in Basarabia there were established 95 new pharmacies. At the classification exam of pharmacists it was found that 546 of them have scored (average) over 15 out of maximum 20. Also in 1941 it was made a general census of pharmacists [15]; so taking into consideration the ethnic origin of the pharmacists, the situation was as follows:

- Romanian pharmacists: 1964 – 79.80 % of total;
- German pharmacists: 288 – 11.70% of total;
- Hungarian pharmacists: 132 – 5.36% of total;
- Other nationality pharmacists: 77 – 3.13% of total.

Considering the pharmacists' occupation the situation was as follows:

- pharmacy owners: 756 – 30.72% of total;
- pharmacy tenants: 45 – 1.83% of total;
- pharmacists who did not practice: 229 – 9.30% of total;
- employed pharmacists: 1431 – 58.15% of total.

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